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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,828

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Yue Hugh Guan

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WASHINGTON, DC 20005

EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

12/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/528,828	Applicant(s) GUAN ET AL.	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-63 is/are pending in the application.
- 4a) Of the above claim(s) 37, 38 and 54-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-36 and 39-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 33-53, in the reply filed on 7/21/2008 is acknowledged. The traversal is on the ground(s) that Groups I and II share a common special technical feature since claim 34 has been amended to recite the phrase "optionally with the application to the teeth, either simultaneously or sequentially, of an additional tooth whitening agent". However, Group II requires "sequential application to the teeth of the additional tooth whitening agent followed by the fluorescent whitening agent", which is a specific step not required by Group I despite the amendment of claim 34.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of 4,4'-bis(2-sulfostryl)biphenyl and salts thereof in the reply filed on 11/19/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Consequently, claims 37, 38 are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology such as "comprises." Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 35, 36, 41 and 43-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "derivatives" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calif. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus*. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art,

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partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful "derivatives" generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of species at page 6, lines 11-21, and these are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-36 and 39-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 33 and 34 recites the broad recitation "enhancing the appearance of the teeth", and the claims also recites "in particular for whitening the teeth" which is the narrower statement of the range/limitation. Claim 39 recites the broad recitation "halogen", and the claim also recites "particularly Cl" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 33-36 and 43-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piechota (US 4,582,701) and in further view of Eckstein et al., (US 4,317,782).

Piechota teaches an anhydrous toothpaste comprising peroxide bleaching compounds and optical brighteners. (See col. 3, lines 67-68; col. 4, lines 18-29.) Optical brighteners are taught to be used at "about 0.01-0.1% by weight", for instance. (See col. 4, lines 14-15.) This amounts to 100ppm to 1000ppm.

Piechota does not teach where the optical brightener is a stilbene derivative.

Ecksteine et al. teach the use of distyryl optical brighteners as additives in toothpastes. (See abstract, and col. 10, lines 20-24.) They teach a compound such as:



, as per claims 33 and 34. Ecksteine et al.

does not teach a method for improving or enhancing the appearance of teeth.

Generally, it is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant's disclosure. See MPEP 2144.06. It is also *prima facie* obvious to select a known material based on its suitability for its intended use. See *Ibid*.

Since Piechota teaches the use of optical brighteners in its toothpaste, and Ecksteine et al. teach adding distyryl optical brighteners to toothpastes, it would have been obvious to select the distyryl compounds of Ecksteine for use in the anhydrous toothpaste of Piechota. The artisan would have been motivated to use a known material based on its suitability for its intended use.

Because the composition of Piechota is a toothpaste, it would have obviously been used for improving the appearance of teeth by applying it to the teeth, consistent with the normal use of toothpastes. The use would have involved a simultaneous application of a peroxide compound and a compound of Ecksteine, as per claim 48, since the compounds are part of a composition.

Since the compounds of Ecksteine meet the structure requirements for the fluorescent whitening agent of claims 33 and 34, they would reasonably be expected to possess the chemical properties of absorbing light of a wavelength less than 380nm and remitting light in the wavelength of 400 to 450¹, as per claim 36.

Adjusting the amount of the distyryl compounds of Ecksteine in the composition of Piechota to less than 100 ppm, as per claims 45 and 46, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the

¹ See for example US Patent. No. 3,223,588 at abstract and col. 1, lines 35-44.

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skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results. See MPEP 2144.05 IIA.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Piechota (*supra*) and Eckstein et al., (*supra*) as applied to claims 33-36 and 43-52 above, and further in view of Rajaiah et al., (US 2002/0187108).

Piechota and Eckstein taken together differ from claim 53 insofar they do not teach a chlorite bleaching agent.

Rajaiah et al. teach the use of peroxides, metal chlorites, and perborates as whitening agents in a toothpaste. (See abstract and [0040].)

Generally, it is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant's disclosure. See MPEP 2144.06. It is also *prima facie* obvious to select a known material based on its suitability for its intended use. See *Ibid*.

Since metal chlorites are recognized as equivalent to peroxides, it would have been obvious to replace the peroxide compound of Piechota with a metal chlorite.

Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piechota (*supra*) and Eckstein et al., (*supra*) as applied to claims 33-36 and 43-52 above, and further in view of Guglielmetti, (US 5,332,861).

Piechota and Eckstein taken together differ from claims 39-42 insofar they do not teach disodium 4,4'-bis(2-sulfostryl)biphenyl, for example.

Guglielmetti teaches distyrylbiphenyl compounds, such as disodium 4,4'-bis(2-sulfostryl)biphenyl, and the use of these compounds as fluorescent whitening agents. (See abstract, and col. 6, lines 41-42.)

When chemical compounds have “very close” structural similarities and similar utilities, without more a prima facie case may be made. In re Wilder, 563 F.2d 457 (CCPA 1957). Stated alternatively, obviousness may be based solely upon structural similarity (an established structural relationship between a prior art compound and the claimed compound, as with homologs). See In re Duel, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

Since the compounds of Eckstein and Guglielmetti have “very close” structural similarities and similar utilities, it would have been obvious to use the compounds of Guglielmetti in the composition of Piechota. The artisan would reasonably expect success in using a fluorescent whitening agent such as disodium 4,4'-bis(2-sulfostryl)biphenyl in the toothpaste composition of Piechota based on these structural and functional similarities.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612